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10/781,506

05/06/2004

Rafail Zubok

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,506

Applicant(s)

ZUBOK ET AL.

Examiner

Jerry Cumberledge

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2004 and 18 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05/02/2005 06/15/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

There exists an inconsistency between the language of claim 1 and that of the claim 4 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 2, line 1, applicant recites "An insertion handle" with an insertion plate being only functionally recited, i.e. "...operable to detachably engage an insertion plate ...", thus indicating that the claim is directed to the subcombination, "An insertion handle". However, in claim 4, lines 2-5, applicant positively recites the insertion plate as part of the invention, i.e. "... the insertion plate includes a base having a posteriorly directed surface...", thus indicating that the combination, insertion handle and insertion plate, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-13 will be considered as being drawn to the combination, insertion handle and insertion plate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9, 10, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Slotman et al. (US Pat. 5,599,279).

Slotman et al. disclose an insertion handle (Fig. 7) comprising: a shaft (Fig. 7, ref. 214) having a proximal end (Fig. 7, end near ref. 212) and a distal end (Fig. 7, end near ref. 222); and an engagement member (Fig. 8, member above ref. 222) disposed at the distal end of the shaft (Fig. 7) and operable to detachably engage an insertion plate (Fig. 7, ref. 218) that maintains first and second members of an intervertebral disc replacement device in registration with one another for substantially simultaneous insertion into an intervertebral disc space of a spinal column. The shaft is operable to permit the first and second members of the intervertebral disc replacement device to be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (Figs. 8 and 9). The insertion handle is detachable from the insertion plate (Fig. 8) to facilitate removal of the insertion handle when the intervertebral disc replacement device is positioned within the intervertebral disc space. The insertion plate includes a base (Fig. 8, below ref. 222) having a posteriorly directed surface (Fig. 8, surface towards ref. 218) directed toward the first and second members of the intervertebral disc replacement device, a spaced apart anteriorly directed surface (Fig. 8, surface towards ref. 220). The insertion handle comprises an actuator (Fig. 1, e.g. ref. 132) disposed substantially at the proximal end of the shaft and operable to cause the shaft and the insertion plate to disengage from one another. The shaft includes a longitudinal bore extending from the proximal end of the shaft toward the distal end (Fig. 10, ref. 224); the insertion handle further comprises

Art Unit: 3733

a pushing member (Fig. 10, ref. 228 bottom) having a proximal end and a distal end (Fig. 10) and being slideably receivable within the longitudinal bore (Fig. 10); and actuation of the proximal end of the pushing member causes the distal end thereof to engage the insertion plate and separate the shaft from the insertion plate. The proximal end of the shaft includes at least one first flange (Fig. 10, flanges of ref. 228 bottom) and the proximal end of the pushing member includes at least one second flange (Fig. 228, flanges of ref. 228 top); and respective forces applied to the first and second flanges facilitates slideable actuation of the pushing member within the longitudinal bore and engagement of the distal end of the pushing member with the stem of the insertion plate to separate the insertion handle from the insertion plate (Fig. 8-10). The urging of the first and second flanges towards one another results in the respective forces to cause the insertion handle and the insertion plate to separate from one another (Figs. 8-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slotman et al. (US Pat. 5,599,279) in view of Wagner et al. (US Pat. 5,683,464).

Slotman et al. disclose the claimed invention except for an insertion member extending away from the anteriorly directed surface of the base; and one of the insertion

Art Unit: 3733

member of the base and the engagement member of the shaft includes a stem and the other of the insertion member of the base and the engagement member of the shaft includes a bore such that the stem is receivable in the bore and the insertion handle and the insertion plate detachably engage one another. At least one of the stem and the bore are sized and shaped for achieving frictional engagement; and at least one of the stem and the bore include tapered surfaces to achieve the frictional engagement. The insertion handle comprises an anti-rotational mechanism disposed at least one of the distal end of the shaft and the stem, the anti-rotational mechanism resisting rotation of the stem within the bore and thereby assisting maintenance of the relative positions of the insertion handle and the intervertebral disc replacement device when they are engaged. The anti-rotational mechanism includes at least one key element disposed on one of the stem and the bore, and at least one slot element disposed on the other of the stem and the bore, the at least one key element and the at least one slot element engaging one another when the stem is disposed in the bore in order to resist rotation of the stem within the bore. The bore is disposed longitudinally within, and terminates at, the distal end of the shaft; and at least two key elements are disposed at the distal end of the shaft and communicate with the bore such that a diameter of the bore terminating at the distal end of the shaft elastically increases as the stem is urged into the bore to facilitate frictional engagement between the stem and the shaft.

Wagner et al. disclose an insertion handle (Fig. 14) with a stem (Fig. 14, ref. 112) and a bore (Fig. 14, ref. 118). The stem is receiveable in the bore in order to detachably engage one another (Fig. 14). The stem includes tapered surfaces to achieve frictional

Art Unit: 3733

engagement (Fig. 10, ref. 112). The stem includes an anti-rotational mechanism (Fig. 10, the shape of the stem, which locks the components together). The antilock mechanism comprises key elements (Fig. 14, left and right flanges of ref. 112) that fit into a bore (Fig. 14, ref. 118). There is an elastic engagement between the stem and the bore, since the components can be made of plastic (column 8, lines 41-51). This arrangement allows the handle and the stem to be firmly yet releasably locked together (column 8, lines 66-67 and column 9, line 1).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Slotman et al. with the stem and bore. The stem is receiveable in the bore in order to detachably engage one another. The stem includes tapered surfaces to achieve frictional engagement. The stem includes an anti-rotational mechanism. The antilock mechanism comprises key elements that fit into a bore. There is an elastic engagement between the stem and the bore, since the components can be made of plastic, all as taught by Wagner et al. This arrangement allows the handle and the stem to be firmly yet releasably locked together (column 8, lines 66-67 and column 9, line 1).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 3733

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,896,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and are thus much more specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)

Art Unit: 3733

272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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